1. What Duloxetine Zentiva is and what it is used for
Duloxetine Zentiva contains the active substance duloxetine. Duloxetine Zentiva is used to treat depression, diabetic neuropathic pain (often described as "pins and needles") in the affected area, or sensations such as touch, heat, cold or pressure may cause pain.

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Duloxetine Zentiva is for oral use. You should swallow it whole. Duloxetine Zentiva is normally taken once a day, during breakfast or dinner.

2. How to take Duloxetine Zentiva
The usual dose of Duloxetine Zentiva is 60 mg once a day. This may be increased to 90 mg or 120 mg a day. The dose can be reduced in certain cases. Duloxetine Zentiva is normally taken once a day, during breakfast or dinner. Duloxetine Zentiva should be taken with or without food. Duloxetine Zentiva can be taken with or without food, drink and alcohol. If you are pregnant or breast-feeding, think you may be pregnant or breast-feeding, or you are planning to become pregnant, you should use Duloxetine Zentiva. You should use Duloxetine Zentiva with caution if you drink alcohol while you are taking it. Duloxetine Zentiva should not be taken with any of these medicines together with Duloxetine Zentiva. You should also tell your doctor if you are taking any of these medicines.

4. Possible side effects
In people with diabetic neuropathic pain it can take some time before you feel better. Your doctor may suggest changing your dose or changing to another medicine if you do not feel better after 2 months. Duloxetine Zentiva may be taken with or without food. Duloxetine Zentiva with food, drink and alcohol

5. How to stop taking Duloxetine Zentiva
If you do not start to feel better after 2-4 weeks, or if the side effects become too troublesome, tell your doctor. You should not take Duloxetine Zentiva if you:

6. Contents of the pack and other information
• are taking other medicines to treat depression (see 'Other medicines and Duloxetine Zentiva');

7. Warnings and precautions
Tell your doctor if you are taking, have taken, or might take any of the following medicines:

8. Other medicines and Duloxetine Zentiva
The following are reasons why Duloxetine Zentiva may not be suitable for you.

9. Driving and using machines

10. Package leaflet: Information for the user

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30 mg once a day after which most patients will receive 60 mg once a day, but your doctor will prescribe the dose that is right for you. The dose may be adjusted up to 120 mg a day based on your response to Duloxetine Zentiva.

To help you remember to take Duloxetine Zentiva, you should take it at the same times each day. Talk with your doctor about how long you will need to keep taking Duloxetine Zentiva. Do not take Duloxetine Zentiva for more than 12 weeks without talking to your doctor. Treating your disorder properly is important to help you get better so if your treatment, your condition may not go away and may become more difficult and difficult to treat.

If you take more Duloxetine Zentiva than you should:

Call your doctor or pharmacist immediately if you take more than the amount of Duloxetine Zentiva prescribed by your doctor. Symptoms of overdose include:

- muscle tightness, muscle twitching;
- vomiting blood, or black tarry stools (faeces);
- throat tightness, nose bleeds;
- fainting, dizziness, light-headedness or fainting on fast and/or irregular heart beat;
- sudden involuntary jerks or twitches of the limbs;
- suicidal thoughts, difficulty sleeping, grinding or clenching of the teeth (may affect up to 1 in 10 people);
- weight loss.

3. How to take Duloxetine Zentiva

Duloxetine Zentiva is a gastro-resistant hard capsule. If you miss a dose, take it as soon as you remember. However, if you are taking more than the missed dose and take only a single dose as usual. Do not take a double dose to make up for the missed dose. Do not take more than the daily amount of Duloxetine Zentiva that your doctor has prescribed for you in one day.

If you stop taking Duloxetine Zentiva

Do NOT stop taking your capsules without the advice of your doctor even if you feel better. If your doctor thinks that you no longer need Duloxetine Zentiva he or she will ask you to reduce your dose over at least 2 weeks before stopping treatment altogether.

Some patients who stop taking Duloxetine Zentiva suddenly have had symptoms such as:

- dizziness, tingling, feelings like pins and needles or electric shock-like feelings (particularly in the hands, feet, mouth, face and eyelids);
- inability to sleep (insomnia);
- feeling of being drunk, fever, sweating or rigid heart.

4. Possible side effects

These symptoms are usually not serious and do not usually disappear within a few days, but if you have symptoms that you think are troublesome you should ask your doctor for advice.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Some of the side effects of Duloxetine Zentiva are:

- muscle tightness, muscle twitching;
- vomiting blood, or black tarry stools (faeces);
- throat tightness, nose bleeds;
- fainting, dizziness, light-headedness or fainting on fast and/or irregular heart beat;
- sudden involuntary jerks or twitches of the limbs;
- suicidal thoughts, difficulty sleeping, grinding or clenching of the teeth (may affect up to 1 in 10 people);
- weight loss.

Very common side effects (may affect more than 1 in 10 people):

- headache;
- feeling sleepy;
- feeling sick (nausea).

Common side effects (may affect up to 1 in 100 people):

- feeling sick;
- constipation;
- diarrhoea, stomach pain, being sick (nausea), feeling of being drunk, fever, sweating or rigid heart.

Uncommon side effects (may affect up to 1 in 1000 people):

- feeling irritable, depression, anxiety, difficulty or failure to experience orgasm, sexual desire;
- trouble sleeping, feeling agitated, less sex drive, anorgasmia;
- increased sweating;
- thirst;
- increased blood pressure, flushing;
- blurred eyesight;
- dry mouth;
- constipation;
- increased appetite;
- joint pain;
- feeling restless;
- feeling dizzy, weak, confused, sleepy or light-headed;
- tiredness or weight gain;
- numbness, pricking or tingling of the skin;
- dark patches on the skin;
- eye pain;
- disturbance of sense of smell or taste;
- throat inflammation that causes a hoarse voice;
- feeling of being drunk, fever, sweating or rigid heart.

Rare side effects (may affect up to 1 in 10,000 people):

- feeling of being drunk, fever, sweating or rigid heart;
- feeling of being drunk, fever, sweating or rigid heart.

Very rare side effects (may affect up to 1 in 100,000 people):

- feeling of being drunk, fever, sweating or rigid heart;
- feeling of being drunk, fever, sweating or rigid heart.

Side effects may also include:

- constipation;
- diarrhoea, stomach pain, being sick (nausea), feeling of being drunk, fever, sweating or rigid heart.

5. How to store Duloxetine Zentiva

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton/blister after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special temperature conditions. Store in the original container in order to protect from moisture.

Do not use this medicine if the container or its stopper is damaged. Ask your pharmacist how to throw away medicines you no longer use. These measures help to protect the environment.

6. Contents of the pack and other information

What Duloxetine Zentiva contains

The active ingredient is duloxetine. Each capsule contains duloxetine hydrochloride equivalent to 30 or 60 mg of duloxetine. The other ingredients are:

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